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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,370	06/30/2003	J. Helen Fitton	2263-1-3	3158
996	7590	01/19/2005	EXAMINER	
GRAYBEAL, JACKSON, HALEY LLP 155 - 108TH AVENUE NE SUITE 350 BELLEVUE, WA 98004-5901			MCCORMICK EWOLDT, SUSAN BETH	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/611,370

Applicant(s)

FITTON ET AL.

Examiner

Susan B. McCormick-Ewoldt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>August 9, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restriction

Applicant's election with traverse of Group III in the reply filed on December 9, 2004 is acknowledged. The traversal is on the ground(s) that the request to reconsider Groups I and II would not require undue searching. This is not found persuasive because the several inventions are distinct and independent from each other; thus, separate searches would be required.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected claims, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 9, 2004.

Claims Pending

Claims 15-21 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19-21 is unclear in the recitation "a weight average molecular weight."

Clarification is needed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 15-16 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujikawa ("Sulphated Polysaccharide of the Thallus of Brown Seaweed *Undaria pinnatifida*," translation provided).

Fujikawa ("Sulphated Polysaccharide of the Thallus of Brown Seaweed *Undaria pinnatifida*,") teaches obtaining a sulphated polysaccharide containing galactose from the thallus of *Undaria pinnatifida* which has a molecular weight of 200,000 or higher (page 2, page 6). The reference does not teach that the polysaccharide has anti-viral properties. However, the composition is the same. Thus, the anti-viral effects would be inherent.

Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Funahashi *et al.* (JP 2002-20403, translation provided).

Funahashi *et al.* (JP 2002-20403) expressly teaches obtaining polysaccharide from brown seaweed (wakame) for the prevention of viral infections. Funahashi *et al.* obtained the polysaccharide from sporophylls of wakame seaweed ([0004]) for the treatment of viral infections ([0016]). The composition is mixed with the necessary medically allowable carriers that can be administered orally ([0017]). Wakame is the common name for *Undaria pinnatifida* as discussed by Applicant on page 5, lines 4-5 of the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Funahashi *et al.* (JP 2002-20403).

A composition for the treatment of viral infections in a mammal comprising galactofucan sulfate obtained from *Undaria*.

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The teaching of Funahashi *et al.* is relied upon for the reasons discussed *supra*. The reference teaches extracting galactose containing polysaccharides from the leaves (sporophylls) of wakame (common name for *Undaria pinnatifida*). The reference teaches that the polysaccharide has anti-viral properties. The reference does not teach using the sporophyll material itself in combination with additional polysaccharide. However, a person of ordinary skill in the art would reasonably expect that the crude sporophyll material would also contain anti-viral properties conveyed by the polysaccharide. Therefore, the artisan of ordinary skill would also reasonably expect that combining the crude sporophyll material with the extracted polysaccharide would produce a product with superior anti-viral properties in comparison with each product alone. Based on this reasonable expectation of success, a person of ordinary skill in the art would have been motivated to combine the extracted polysaccharide with sporophyll material.

This reference does not specifically teach adding the ingredients together in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result-effective parameter that a person of ordinary skill in the art would routinely optimize. This is recognized in the reference in paragraph 21 ([0021]). Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill to employ. It would have been customary for an artisan to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration for unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of the Applicant's invention.

The reference also does not specifically teach that the polysaccharides have the molecular weights claimed by Applicant. However, a person of ordinary skill in the art would be motivated to modify the extraction parameters to obtain different molecular weight polysaccharides in order to best achieve the pharmaceutical effects taught by the reference.

Claims 15 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujikawa *et al.*

As discussed above, Fujikawa *et al.* teaches sulfated galactofucan obtained from *Undaria*. The reference teaches that the polysaccharide has a molecular weight of 200,000 or

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higher but does not specifically disclose all of the molecular weights claimed by Applicant. However, the extraction parameters taught by the reference can be optimized to obtain different polysaccharides to meet the needs of an artisan of ordinary skill. Such an optimization would be routine practice in the art. Thus, it is considered obvious to modify the polysaccharide of Fujikawa *et al.* to obtain polysaccharides of different molecular weight.

Summary

No claim is allowed.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

Susan D. Coe
1-14-05

SUSAN D. COE
PATENT EXAMINER